



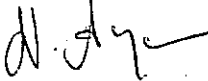

**Management Review Meeting of SNSC performance based on Internal Audit**


**Audit cycle – II (2015), Jul to Dec 2015 : Dated 13.02.2016**

**Attendance:** By list (list enclosed). The representations were from the SN main lab for Hematology and Clinical Pathology, Clinical Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics and the Support Services, CSFU, HRD, Commercial, Biomedical, Electrical, Training Dept, IT, All Internal auditors & NABH - Coordinator

**The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.**

- a) The periodic review of requests, and suitability of procedures and sample requirements.
- b) Assessment of user feedback.
- c) Staff suggestions.
- d) Internal audits.
- e) Risk management.
- f) Use of quality indicators.
- g) Reviews by external organizations.
- h) Results of participation in inter laboratory comparison programmes (PT/EQA).
- i) Monitoring and resolution of complaints.
- j) Performance of suppliers.
- k) Identification and control of nonconformities.
- l) Results of continual improvement including current status of corrective actions and preventive actions.
- m) Follow-up actions from previous management reviews.
- n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system.
- o) Recommendations for improvement, including technical requirements.

Issue Date : 15.02.2016		Page 1 of 11
Prepared & Issued by: Quality Manager 	Approved by: Management Representative 	

	<b>SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY</b> (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the MRM Review Meeting - 19
	ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -19	

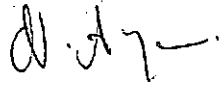

**Audit Team Members and Audited labs/Support services** : Internal audit conducted based on new standard ISO 15189 : 2012 for the following departments

- Quality System : : Ms.K.Vanitha
- Front Office & Pre analytical area : Ms.R.Punitham
- Clinical Pathology and Hematology : Ms.R.Punitham
- Clinical and Special Biochemistry : Dr.J.Malathi
- Clinical Microbiology and Serology : Ms.U.Jayanthi
- Histopathology and Cytopathology : Ms.R.Punitham
- Human Resource Department : Ms.R.Punitham
- Commercial : Ms.Saumya.T.S
- Central Sterilization Facility Unit : Ms.U.Jayanthi
- Biomedical Department : Ms.Saumya.T.S
- Information Tech Dept : Ms.R.Punitham
- SNSC Collection Centre : Dr.N.Angayarkanni
  
- **Non-NABL**
- Genetics : Ms.Rajalakshmi
- NSN Lab : Dr.B.Mahalakshmi

a. **The periodic review of requests, and suitability of procedures and sample requirements** :

This has been reviewed for the two quarters in the last 6 months, dept wise. Corrective actions were taken wherever applicable.

- Sound Proof room for pediatric collection is in use from March 2015.
- ACL ELITE PRO installation has been completed (cl. Hematology) and has been put to use in patient care services from 15.12.15 for same has been informed to NABL office on 21stJan'16.

Issue Date : 15.02.2016		Page 2 of 11
Prepared & Issued by:	Approved by:	
Quality Manager 	Management Representative 	



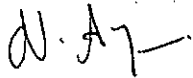
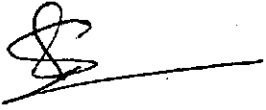
- Antibodies to Aquaporin 4 (Test Code L-233) - Immunofluorescence Method (New test) has been included in the NABL from 26th August 2015.
- Antibodies to Aquaporin 4 (AQP4/NMO) Code no: L-233 changed the frequency of testing from once a day in a week to three days (Monday, Wednesday and Friday) of every week. The reports for the same test will be available on the respective days at 5:30pm for all the specimens received by 11:00am on the test scheduled days.
- Ms. B. Hema (Emp.No.1104376) has been designated as Junior Scientist and has been given an additional responsibility of "Deputy Technical Manager" for SNSC Clinical Microbiology & Serology Laboratory w.e.f.15.10.2015
- Dr.Doreen Gracias, MBBS, DCP, PhD, is delegated to supervise the routine Clinical Biochemistry as a signing authority. She shall co-ordinate with Dr.N.Angayarkanni, Head, Clinical Biochemistry w.e.f.15.06.2015
- Dr.N.Angayarkanni, Ph.D, is given the authority as Quality Manager for the SNSC lab, since 21st September 2005. She shall continue to report to the Director of Laboratory Services / Management Representative of SNSC lab as QM for the ISO 15189: 2012.

**b. Assessment of user feedback :**

This analysis is done in SN-Main lab (Cl.Haematology, Cl.Pathology, Cl.Biochemistry & SNSC Collection Centre – Pycrofts Road), Microbiology and Histopathology labs.

*Internal customer feedback :* The observed measures (Jul - Dec'15) were above the objective in all the laboratories.

- Histopathology & Cytopathology (Jul - Dec'15) - 91% (Objective - 80%)
- Microbiology & Serology (Jul - Dec'15) - 92% (Objective - 80%)
- Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and SNSC Collection Centre - Pycrofts Road) (Jul - Dec'15) - 86% (Objective - 80%)

Issue Date : 15.02.2016			Page 3 of 11
Prepared & Issued by:	Approved by:		
Quality Manager 	Management Representative		



*External customer feedback:*

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry  
(Jul - Dec'15) - 90% (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road (Jul - Dec'15) - 88% (Objective - 80%)

**c. Staff suggestions :** 19 (Jul - Dec'15)

Approved - 1 (Opaque sheet on the glass window to prevent sunlight)

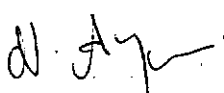

Not Approved – 18 (Most of it was on salary improvement and has been forwarded to HR.  
The rest were on environmental issues)

**d. Internal audits :**

- Internal audit - II (2015) conducted by Internal Assessors based on New Standard ISO 15189 : 2012, all the NCs have been closed on stipulated time interval.  
(Minor NC-28, Major NC-20): All are closed.
- External audit (May 30<sup>th</sup> & May 31<sup>st</sup>) conducted by External Assessors based on New Standard ISO 15189:2012, all the NCs corrective action has been taken in stipulated time interval (Minor NC -11, Major NC – 3)
- NABL recommended for renewal of accreditation in accordance with ISO 15189:2012.  
Certificate Validity period : 14.08.2015 - 13.08.2017

**e. Risk management : (Based on CAPA)**

- Clinical Hematology : Wrong reporting / improper verification / not repeating when required/ in –coordination between technician in reporting .
- Clinical Biochemistry: change of code no while reporting, release of report before the completing the report, two reports for the same sample in two machines, in –coordination between the technicians.
- The laboratory was closed due to heavy flood on 03.12.15 to 05.12.15 in Chennai.

Issue Date : 15.02.2016			Page 4 of 11
Prepared & Issued by: Quality Manager		Approved by: Management Representative	

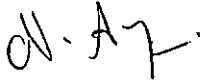
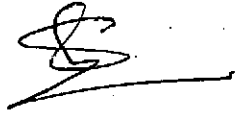


f. **Use of quality indicators** : Quarterly reports submitted by all the labs / collection centre, monitored by QM.

- **Pre Analytical** : Sample collection, Transport-time, Repeat & Rework : All are within the objective (Jul - Dec'15)
- **Analytical** : (Internal & External QC, Equipment down time) All are within the objective From Jul - Dec'15 except : Clinical Biochemistry - EQAS, IQC & Equipment Down Time (Dade Dimension), Microbiology - EQAS & Equipment Down Time (Cytospin, Laminar Flow Hood) : CAPA documented
- **Post Analytical** : (Turnaround time, Amendment test reports) All are within the objective From Jul - Dec'15 except : Clinical Biochemistry, Histopathology - Turn around time : CAPA documented.
- All the Dy Technical managers are requested to display the quantitative measures, in the form of graph. (Quarterly/half-yearly/one year data with a comparison of the previous corresponding set)
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 6 months From Jul - Dec'15, dept wise. Corrective actions were taken wherever applicable.

g. **Reviews by external organizations** :

- Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012 (Validity till 19.02.2016) for SN Main Hospital & SNSC Centre at Pycrofts road, Chennai.
- Absolute Alcohol Renewal of license done on April'15. Valid upto Mar-2016.
- GJ Multiclave (For Biomedical waste) renewal has been done on May 2015 for SN Main, SNSC Collection centre – Pycrofts road (Valid upto May 2018)

Issue Date : 15.02.2016			Page 5 of 11
Prepared & Issued by:	Approved by:		
Quality Manager 	Management Representative		



- Biomedical Department : Renewal of Calibration Certificate done From Jul - Dec'15
  - Digital Multimeter - 25.08.2015 – 25.08.2016
  - Digital Tachometer - 11.09.2015 – 11.09.2016
  - Weight box - 11.12.2015 – 11.12.2016
  - Indicator with Sensor - 20.04.2015 – 20.04.2016
  - Digital stopwatch - 23.12.2015 – 23.12.2016
  - BP Apparatus - 11.12.2015 – 11.12.2016
  - Glass Thermometer - 14.12.2015 – 14.12.2016
- Maintenance Department : Renewal of Calibration Certificate done From Jul – Dec'15
  - Temperature Indicator with Sensor - 28.11.2015 – 28.11.2016
  - Hygrometer - 28.11.2015 – 28.11.2016

**h. Results of participation in inter laboratory comparison programmes (PT/EQA) :**

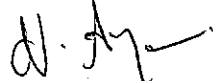

- This has been reviewed for the two quarters in the last 6 months, From Jul - Dec'15 dept wise : Satisfactory Results.
- MOU with Lister lab for Inter Lab Comparison : renewal has been made and valid till July 2017.

**i. Monitoring and resolution of complaints :**

- Based on Internal & External feedback forms (Jul - Dec'15) actions were taken and the issues settled (as in point b)

**j. Performance of suppliers :**

- Vendor evaluation completed for the period of (Jul - Dec'15) is given by commercial dept.
- Vendor Complaint for the period of (Jul - Dec'15) : 5 Complaints (Settled)

Issue Date : 15.02.2016			Page 6 of 11
Prepared & Issued by:	Approved by:		
Quality Manager 	Management Representative		



**k. Identification and control of nonconformities :**

- Daily non conformances are documented in all the laboratories and discussed in the respective Departmental lab meetings for corrective action. CAPA are documented for detailed ones.
- As requested by QM, all technical and non-technical staff including secretaries are encouraged to independently state the daily NC in the records followed by supervisors' attestation.

**l. Results of continual improvement including current status of corrective actions and preventive actions :**

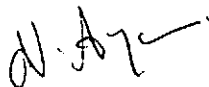

**Continual Improvement : (Jul to Dec 2015)**

**Quality System :**

- Renewal of NABL Accreditation for SNSC Clinical Laboratory.
- SOP for External services and supplies and Stores- Approved vendor list period, Inspection criteria for material receiving has been updated.
- Rubber stamp with revised details has been provided for respective dept for material receiving (used in Delivery Chelan)
- SOP for Authority & Responsibility - Microbiology & Histopathology lab secretary job responsibilities has been included.
- Color coding system has been implemented in HMS for specimen (Green: accepted; Pink: yet to be accepted)

**Haematology & Clinical Pathology :**

- ACL ELITE PRO Fully Automated Analyzer (for Coagulation Testing) has been installed on Sep'15 communicated to NABL office on 27th January 2016

Issue Date : 15.02.2016		Page 7 of 11
Prepared & Issued by: Quality Manager 	Approved by: Management Representative 	



- Blood Transfer Device Started using for Pediatric blood collection along with mini collectors & winged butterfly needle set w.e.f.08.10.2015.
- Training Programme attended by (i). Ms.Logeshwari, Ms.Suganya & Ms.Jayshree topic entitled "Pre Analytical Variables" conducted by Crest Laboratories on 28.07.2015  
(ii). Ms.Sowmiya E.R.,Ms.Shanthi attended "Phlebotomist Training" conducted by Value Added Corporate Services on 16.10.2015
- New Flush Tank Installed in the Indian toilet as per patient suggestion (Dec 15)
- REH Collection Centre started on 22nd October 2015 (Non NABL)

**Clinical & Special Biochemistry**

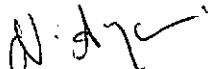

- Improved Sensitivity of HbA1C method : (NGSP Certified) got quotation and kits are procured (Method validation in process) (Non NABL)
- Review of Samples : suggested Heparin sample collected instead of Plain sample for LFT and Lipid Profile tests (Validation in process).
- CME Programme attended by Ms.R.Punitham titled "Total Quality Management in Laboratory Medicine" and "Quality Management in Clinical Laboratories"

**Histopathology lab :**

- Updated SNOWMED code in HMS
- Proficiency Test conducted for Special Stains once in 4 months.
- Dr.S.Krishnakumar attended ISO 15189 : 2012 Internal Audit & Quality Management

**Microbiology lab :**

- Automated analysis using VITEK compact for identification & Antibiotic Susceptibility Test for Bacteria and yeast identification.
- MIC of the test organism to Vancomycin and Pencicillin by E-Test
- Time is reduced and Objective are increased by few percentages for reporting direct smear reports to consultants and generation of reports, completion of rapid screening method,

Issue Date : 15.02.2016			Page 8 of 11
Prepared & Issued by: Quality Manager		Approved by: Management Representative	





generation of aerobic, anaerobic, serology reports, time of uploading soft copy reports of critical alert.

- For verifying soft copy of reports, a schedule has been prepared.

**Corrective action & Preventive action :**

- Quality Control Programme : Internal and External QC, ILQC, PT programme in each of the lab has been verified. The labs have taken appropriate corrective actions as required
- Measure on QC is verified quarterly by QM as part of Quality Indicator.

**m. Follow-up actions from previous management reviews :**



- SNSC Staff members attended CME Programme by ISRO Tele Ophthalmology Dept
- Requisition form to be made in HMS- shall be followed up with Dr.Sudhir and IT
- Internal training (Soft skill training) programme conducted through training department.
- Internal and external training details are documented and verified by QM.

**n. Changes in the volume and scope of work, personnel, and premises that affect QMS :**

**List of NABL Accreditation tests at SNSC Clinical laboratory approved in the recertification audit (validity) :**

- Clinical Haematology : 20 and Clinical Pathology : 19
- Clinical and Special Biochemistry : 19
- Clinical Microbiology and Serology : 27
- Histopathology : 7 and Cytopathology - 4

**Total: 96 Tests**

Issue Date : 15.02.2016			Page 9 of 11
Prepared & Issued by:	Approved by:		
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**Staff adequacy:** Adequate.

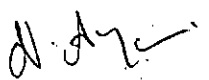
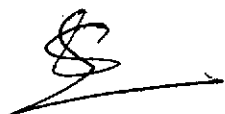
**Resignations /Appointments:**

- Microbiology: One Lecturer : Dr.B.Mahalakshmi  
One Associate Professor : Dr.R.Gayathri  
One Junior Executive : Ms.Faritha Banu  
Two Senior Lab Technicians : Ms.Saranya & Ms.Dhanalakshmi
- Haematology: Junior Executive : Ms. Priya
- Biochemistry Lab : One Lecturer : Dr.K.Coral  
One Junior Executive : Ms.Padma  
One Lab Technician : Ms.Najumunisha Begum
- Cytogenetics (Non NABL) : One Secretary : Ms.Jothilakshmi.

**Appointments :Refilling of the post:**

- Microbiology : One Junior Executive : Mr.Kaviarasu  
Four Lab Technicians : Ms.Isabella Mary, Ms.Priyanka, Ms.Ramya &  
Mr.Tamizhan.
- Haematology: Lab Technician : Ms.Suganya
- Biochemistry : One Junior Executive : Ms.Brindha  
One Lab Technician : Ms.Saranya
- Cytogenetics (Non NABL) : One Secretary : Ms.Rekha

**Promotions:** Nil

Issue Date : 15.02.2016		Page 10 of 11
Prepared & Issued by: Quality Manager 	Approved by: Management Representative 	



**SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

**ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING - 19**

Minutes of the  
MRM Review  
Meeting - 19

**Document control: Version numbers of documents revised in 2015 (Jul - Dec'15) :**

**Quality System :**

- Consent form for HIV Testing : CPAPM 4.2
- Lab Requisition Form : F/SNSC/ML/LRF/1.18
- Referral Laboratory Evaluation Form : SNSC/REF/2015/Ver-1.4
- Customer Feed Back Form (Histopathology) : SNSC/CFF/OP-Rev.2
- Format for Grossing Details : F/SNSC/OP/GD-Version 1.3
- Corrective & Preventive Action Report : SNSC/C&P/2016/Version-1.4

**o. Recommendations for improvement, including technical requirements :**


- Biomedical Department provided Preventive Maintenance / Calibration plan for the year 2016 made uniform in Laboratory and Biomedical Engineering
- Material specification sheet to be strictly implemented
- Staff suggestion to be encouraged and acted upon
- Requisition form to be made in HMS- shall be followed up
- Test request raised by Consultant / Assistant for OT specimens for Microbiology & Histopathology tests shall be followed up
- Daily NC and CAPA to be adequately addressed and documented by each lab.

**Thank You**



  
**Dr. N. Angayarkanni,**


Quality Manager,  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai - 600 006.

**Forwarded by:**

  
**Dr.S.B.Vasanthi**  
Management Representative  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai - 600 006.

**Date: 15.02.2016**

Issue Date : 15.02.2016			Page 11 of 11
Prepared & Issued by: Quality Manager 	Approved by: Management Representative 		

	<b>SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY</b> (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the Management Review Meeting - 20
	ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20	

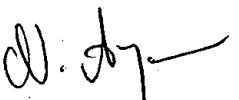
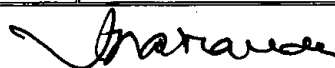
**Management Review meeting of SNSC Clinical Laboratory performance based on**

**Internal Audit cycle – I, Jan to Jun 2016: Dated 22.09.2016**

**Attendance:** By list (list enclosed). The representations were from the SN main lab for Hematology and Clinical Pathology, Cl.Biochemistry, Microbiology and Serology, Histopathology & Cytogenetics.

**The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.**

- a) The periodic review of requests, and suitability of procedures and sample requirements.
- b) Assessment of user feedback.
- c) Staff suggestions.
- d) Internal audits.
- e) Risk management.
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- o) Recommendations for improvement, including technical requirements.

Issue Date : 22.09.2016		Page 1 of 11
Prepared & Issued by:  Quality Manager 	Approved by:  Deputy Management Representative	



**SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20

Minutes of the  
Management  
Review  
Meeting - 20

**Audit Team Members and Audited labs/Support services** : Internal audit conducted based on new standard ISO 15189 : 2012 for the following departments

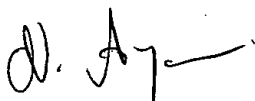
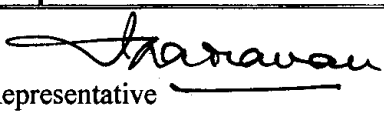
- Quality System : Dr.J.Malathi
- Front Office & Pre analytical area : Ms.K.Vanitha & Dr.S.Sripriya
- Clinical Pathology and Hematology : Ms.K.Vanitha & Dr.S.Sripriya
- Clinical and Special Biochemistry : Ms.Rajalakshmi & Ms.Hema
- Clinical Microbiology and Serology : Ms.R.Punitham & Dr.S.R.Bharathi Devi
- Histopathology and Cytopathology : Ms.Saumya.T.S
- Human Resource Department : Ms.Saumya.T.S & Ms.Hema
- Commercial : Dr.N.Angayarkanni & Dr.S.R.Bharathi Devi
- Central Sterilization Facility Unit : Ms.Rajalakshmi
- Biomedical Department : Dr.N.Angayarkanni & Dr.S.R.Bharathi Devi
- Information Tech Dept : Ms.Saumya.T.S & Ms.Hema
- SNSC Collection Centre (Pycrofts Road) :Ms.U.Jayanthi
  
- **Non-NABL**
  - SNSC Collection Centre (NSN) : Ms.U.Jayanthi
  - Cytogenetics : Ms.R.Punitham

a. **The periodic review of requests, and suitability of procedures and sample requirements** :

This has been reviewed for the two quarters in the last 6 months, dept wise. Corrective actions were taken wherever applicable.

- NABL Logo has been implemented for PT, APTT report from 28.04.2016
- Collection Centre at HTP block has been shifted to Siva Sailam Block on 02.05.2016.

The shifting detail has been sent to NABL office on 23.05.2016.

Issue Date : 22.09.2016		Page 2 of 11
Prepared & Issued by: Quality Manager 	Approved by: Deputy Management Representative 	



**SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20

Minutes of the  
Management  
Review  
Meeting - 20

- As per NABL standard 112 (Clause 5.5) two of the parameters included in Hematology report format on 15.02.2016 :
  - (i). Differential counts: Both Relative and Absolute counts.
  - (ii). Red cells distribution width (RDW) included along with the blood indices.

**b. Assessment of user feedback :**

This analysis is done in SN-Main lab (Cl.Haematology, Cl.Pathology, Cl.Biochemistry & SNSC Collection Centre – Pycrofts Road), Microbiology and Histopathology labs.

*Internal customer feedback:* The observed measures (Jan - Jun'16) were above the objective in all the laboratories.

- Histopathology & Cytopathology (Jan - Jun'16) - 92% (Objective - 81%)
- Microbiology & Serology (Jan - Jun'16) - 88% (Objective - 80%)
- Main lab (Hematology, Cl.Pathology , Cl.Biochemistry and SNSC Collection Centre - Pycrofts Road) (Jan - Jun'16) - 90% (Objective - 80%)

*External customer feedback:*

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry (Jan - Jun'16) - 91% (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road (Jan - Jun'16) - 88% (Objective - 80%)

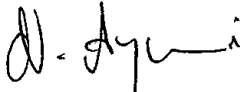
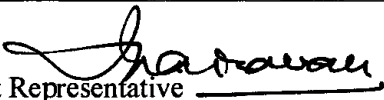
**c. Staff suggestions : 4 (Jan - Jun'16)**


Approved - 3 : (i). Mantoux reading date mentioned in the collection area notice board.

(ii). Provide sterile tissue paper for swab collection patients.

(iii). Back rest revolving stools / chairs for microscope & report verification.

Not Approved-1:(i).Name board for HOD room, Paediatric collection area & Swab collection area

Issue Date : 22.09.2016			Page 3 of 11
Prepared & Issued by: Quality Manager 		Approved by: Deputy Management Representative 	

	<b>SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY</b> (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the Management Review Meeting - 20
	ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20	

**d. Internal audits :**

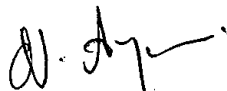
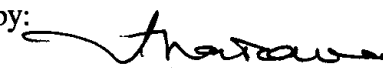
- Internal audit - I (2016) conducted by Internal Assessors based on New Standard ISO 15189:2012, all the NCs have been closed on stipulated time interval. (Minor NC-22, Major NC-13): All are closed.
- NABL conducted desktop audit on July'16, NABL recommended for renewal of accreditation in accordance with ISO 15189:2012. Certificate Validity period : 14.08.2015 - 13.08.2017

**e. Risk management : (Based on CAPA)**

- Clinical Hematology: Mantoux injection given to the wrong patient.
- ESR parameter value was verified and authorized without updating the value.
- Clinical Biochemistry : Critical alert was wrongly updated into another patient's file

**f. Quality indicators :** Quarterly reports submitted by all the labs / collection centre, monitored by QM.

- Pre Analytical : Sample collection, Transport time, Repeat & Rework : All are within the objective (Jan - Jun'16) except : Special Biochemistry – Repeat test.
- Analytical : (Internal & External QC, Equipment down time) All are within the objective From Jan - Jun'16 except : Haematology – EQAS, Clinical Biochemistry – EQAS & IQC, Special Biochemistry – IQC, Microbiology - Equipment Down Time (Autoclave) : CAPA documented
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From Jan - Jun'16 except : Microbiology, Histopathology & Special Biochemistry - Turn around time : CAPA documented.

Issue Date : 22.09.2016		Page 4 of 11
Prepared & Issued by: Quality Manager 	Approved by:  Deputy Management Representative	



**SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**



ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20

Minutes of the  
Management  
Review  
Meeting - 20


- All the Dy Technical managers are requested to display the quantitative measures, in the form of graph. (Quarterly/half-yearly/one year data with a comparison of the previous corresponding set).
- Additional faculty has been appointed in the clinical Biochemistry for supervision.
- Most of the technical staff and faculty in the SNSC cl lab attended the seminar on Medical laboratory technology "Emerging Trends in Laboratory Diagnostics" on 25.06.2016 conducted by the SN Academy.
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 6 months From Jan - Jun'16, dept wise. Corrective actions were taken wherever applicable.

**g. Reviews by external organizations :**

- Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012 (Validity till 19.02.2016) for SN Main Hospital & SNSC Centre at Pycrofts road. Renewal under process.
- Absolute Alcohol Renewal of license done on Mar'16, Valid upto Mar-2017.
- GJ Multiclave (For Biomedical waste) renewal has been done on May 2015 for SN Main, SNSC Collection centre – Pycrofts road (Valid upto May 2018)
- Biomedical Department : Renewal of Calibration Certificate done From Jan - Jun'16
  - Temperature Indicator with Sensor - 20.04.2016 – 20.04.2017
  - Digital Multimeter - 25.08.2016 – 25.08.2017
- Maintenance Department : Renewal of Calibration Certificates
  - Temperature Indicator with Sensor - 28.11.2015 – 28.11.2016
  - Hygrometer - 28.11.2015 – 28.11.2016

Issue Date : 22.09.2016		Page 5 of 11
Prepared & Issued by: Quality Manager 	Approved by: Deputy Management Representative 	



	<b>SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY</b> (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the Management Review Meeting - 20
	ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20	

**h. Results of participation in inter laboratory comparison programmes (PT/EQA) :**

- This has been reviewed for the two quarters in the last 6 months, From Jan - Jun'16 dept wise : Satisfactory Results.
- MOU with Lister lab for Inter Lab Comparison : renewal has been made and valid till July 2017.

**i. Monitoring and resolution of complaints :**

- Based on Internal & External feedback forms (Jan - Jun'16) actions were taken and the issues settled (as in point b)

**j. Performance of suppliers :**

- Vendor evaluation done for the period of (Jan - Dec'16) is given by commercial dept.
- Vendor Complaint for the period of (Jan - Jun'16) : 3 Complaints (Settled)

**k. Identification and control of nonconformities :**


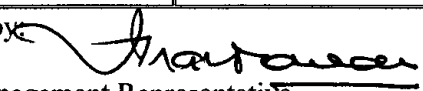
- Daily non conformances are documented in all the laboratories and discussed in the respective departmental lab meetings for corrective action. CAPA are documented for detailed ones.
- As requested by QM, all technical and non-technical staff including secretaries is encouraged to independently state the daily NC in the records followed by supervisors' attestation.

**l. Results of continual improvement including current status of corrective actions and preventive actions :**

**Continual Improvement : (Jan - Jun 2016)**

**Quality System :**

- NABL conducted onsite assessment for Haematology lab on 02.03.16 for the verification of installation of ACL ELITE PRO, External auditor - Dr.Anila Anna Mathan. All the NCs has been closed.

Issue Date : 22.09.2016		Page 6 of 11
Prepared & Issued by: Quality Manager		Approved by  Deputy Management Representative



**SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

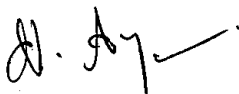
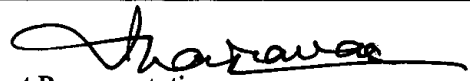
ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20

Minutes of the  
Management  
Review  
Meeting - 20

- Dr.S.Sripriya, Dr.S.R.Bharathi Devi & Ms.B.Hema attended Internal Audit & Quality Management System Certificate Course (4 days) at Saveetha Medical College, Chennai on 11th May – 14th May 2016.
- NABL conducted desktop audit on July'16, NABL recommended for renewal of accreditation in accordance with ISO 15189:2012. Certificate Validity period : 14.08.2015 - 13.08.2017
- SOP for Master list of forms and records are segregated department wise.
- SOP for Organization profile, Accommodation and Environmental conditions, Personnel, Stores, External Services and Supplies, Laboratory equipment reagents and consumables has been updated.
- Updated SOP on External services and supplies, Laboratory Equipment Reagents and Consumables controlled copy was given to commercial department and biomedical department. The SOP for the Personnel controlled copy was given to HRD.
- SNSC Staff members attended seminar on Medical laboratory technology “Emerging Trends in Laboratory Diagnostics” on 25.06.2016.
- Dr.Spandana MD Biochemistry joined in the department of Biochemistry for supervision of the clinical and special clinical biochemistry on 17<sup>th</sup> August 2016

**Haematology & Clinical Pathology :**

- Haematology reporting of results : Included RDW & Absolute counts (DC) in routine work up w.e.f.15.02.2016
- Daily Quality Control for blood grouping reagents : Included Rh Negative cells also for checking w.e.f.30.06.2016
- Ms.Saumya attended CME Programme attended “CME on Recent Trends In Laboratory Medicine” program on 16.04.16 organized by Billroth Hospital, Chennai.
- Beckman fully automated urine analyzer is being contemplated.

Issue Date : 22.09.2016			Page 7 of 11
Prepared & Issued by: Quality Manager		Approved by: Deputy Management Representative	



**Clinical & Special Biochemistry**

- Ms.Gayathri attended “CME on Recent Trends In Laboratory Medicine” program on 16.04.16 organized by Billroth Hospital, Chennai.
- Ms.R.Punitham, Ms.Gayathri, Ms.U.Jayanthi attended the seminar on Medical laboratory technology “Emerging Trends in Laboratory Diagnostics” on 25.06.2016 conducted by the SN Academy. Dr.AK as part of the organizing team participated in the same.

**Histopathology lab :**

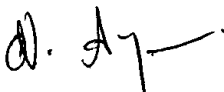
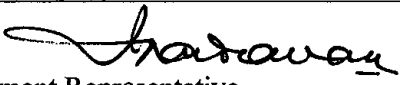
- Participation of ILQA (conducted by Anand laboratory, Bangalore) Renewal has been done for the year 2016.

**Microbiology lab :**

- Antibodies to Aquaporin - 4 test has been included for Inter Laboratory Comparison (ILC) and is scheduled for twice a year
- Senior technical staff are also trained to type and upload the Microbiology and Serology test reports in order to generate HMS reports in the absence of secretary.
- Mr.K.Kaviyaran & Ms.E.Isabella Mary attended “CME on Recent Trends In Laboratory Medicine” program on 16.04.16 organized by Billroth Hospital, Chennai.

**Corrective action & Preventive action :**

- Quality Control Programme: Internal and External QC, ILQC, PT programme in each of the lab has been verified. The labs have taken appropriate corrective actions as required
- Measure on QC is verified quarterly by QM as part of Quality Indicator.

Issue Date : 22.09.2016			Page 8 of 11
Prepared & Issued by: Quality Manager 		Approved by: 	
		Deputy Management Representative	



**m. Follow-up actions from previous management reviews :**

- Requisition form to be made in HMS- is yet to be completed by the IT team.
- Internal training (Soft skill training) programme conducted through training department.
- Internal and external training details are documented and verified by QM.

**n. Changes in the volume and scope of work, personnel, and premises that affect QMS :**

**List of NABL Accreditation tests at SNSC Clinical laboratory approved in the recertification audit (validity) :**


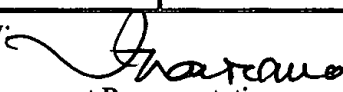
- Clinical Haematology : 20 and Clinical Pathology : 19
- Clinical and Special Biochemistry : 19
- Clinical Microbiology and Serology : 27
- Histopathology : 7 and Cytopathology - 4

**Total: 96 Tests**

**Staff adequacy:** Adequate.

**Resignations :**

- Microbiology: One Junior Executive : Ms.Revathy Menon
- Haematology: One Lab Assistant : Ms.E.R.Sowmiya,  
Lab Technician : Ms.Roja  
One Secretary : Ms.Asvini
- Biochemistry Lab : One Junior Executive : Ms.Brindha
- Histopathology Lab : One Lab Technician : Ms.Thenmozhi
- Cytogenetics (Non NABL) : Head of the Department : Dr.A.J.Pandian  
One Secretary : Ms.Rekha

Issue Date : 22.09.2016		Page 9 of 11
Prepared & Issued by: Quality Manager 	Approved by:  Deputy Management Representative	



**SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

**ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20**

Minutes of the  
Management  
Review  
Meeting - 20

**Appointments :Refilling of the post:**

- Microbiology : One Junior Executive : Ms.Janaki
- Haematology: One Junior Executive : Ms.Hema  
One Lab Assistant : Ms.Vineetha  
One Secretary : Ms.Revathi
- Biochemistry : Assistant Professor : Dr.T.Spandana  
One Lab Technician : Ms.Logeswari
- Cytogenetics (Non NABL) : Senior Professor /HOD : Dr. Sinnakarupan Mathavan  
One Secretary : Ms.Jeevajoithi  
One Social Worker : Mr.Venkatesan

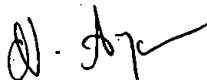
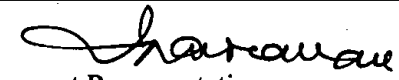
**Promotions:**

- Dr. K. Lily Therese re-designated as "Senior Chief Scientist / Senior Professor / HOD of Microbiology" w.e.f.01.07.16.
- Dr.J.Malathi re-designated as "Senior Principal Scientist" w.e.f.01.06.16
- Ms.Pameswari promoted to Senior Executive (E3) w.e.f.01.01.16
- Ms.Tamil Selvi, Ms.T.S Saumya, Ms.Rajalakshmi, Ms.Gayathri & Mr.Ravikumar promoted to Executive (E2) w.e.f.01.01.16
- Mr.Venugopal promoted to Senior helper w.e.f.01.01.16

**Document control: Version numbers of documents revised in 2016 (Jan - Jun'16) :**

**Quality System :**

- Lab Requisition Form : F/SNSC/ML/LRF/1.19
- Checklist for Medical Laboratories Collection Centre : SNSC/CC-CL/2016/Ver-1.1
- Quarterly reporting of the Dy.Technical Managers to the Quality Manager on Continual Improvement : SNSC/QR/2016/Ver-1.8
- SNSC Collection Centre Quarterly reporting to Quality Manager on Continual Improvement : SNSC/QR-CC/2016/Ver-1.2

Issue Date : 22.09.2016		Page 10 of 11
Prepared & Issued by: Quality Manager 	Approved by:  Deputy Management Representative	



**SRI NATHIELLA SAMPATHU CHETTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)**

**ISO 15189:2012 - MANAGEMENT REVIEW MEETING -20**

Minutes of the  
Management  
Review  
Meeting - 20

**o. Recommendations for improvement, including technical requirements :**

- Material specification sheet to be strictly implemented with amendments in place whenever amended and vendor complaints to be documented
- Staff suggestion to be encouraged and acted upon
- Requisition form to be made in HMS- shall be followed up with the IT team
- Test request raised by Consultant / Assistant for OT specimens for Microbiology & Histopathology tests shall be followed up with the IT team.
- Daily NC and CAPA to be adequately addressed and documented by each lab.

**Thank You**

  
**Dr. N. Angayarkanni,**

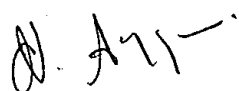
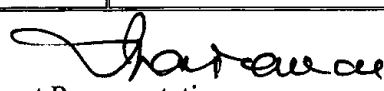
Quality Manager,  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai – 600 006.

**Forwarded by:**



**Dr.H.N.Madhavan**  
Deputy Management Representative  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai – 600 006.

**Date: 22.09.2016**

Issue Date : 22.09.2016		Page 11 of 11
Prepared & Issued by: Quality Manager 	Approved by:  Deputy Management Representative	